

REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and following remarks.

Applicants appreciate the Examiner's and the supervisor's courtesy in having the telephone interview on March 1, 2011 and sending the interview Summary on March 13, 2011. The substance of the discussion has been incorporated in the remarks below.

Claim 6 has been amended editorially. Withdrawn claim 10 has been amended editorially.

Claim 6 has been objected to due to lack of an antecedent basis. Claim 6 has been amended as suggested in the Office Action mailed on November 22, 2010. Accordingly, this objection should be withdrawn.

Claims 1-6 and 11-13 have been rejected under 35 U.S.C. 102(b) as being anticipated by Sue et al. (U.S. Patent Application Publication No. 2002/01320006). Applicants respectfully traverse this rejection.

Claim 1 is directed to a ready mix flavored composition for film coating of a pharmaceutical oral solid dosage form comprising a polymer and a flavoring agent, but no sweetening agent, where the composition masks an unpleasant taste of a solid core of the pharmaceutical oral solid dosage form. By excluding the sweetening agent, for example sugar, the pharmaceutical dosage form can be taken by diabetic patients and can avoid a thick coating that may increase a weight and size of the tablet, dissolving time thereof, and time necessary for manufacturing the tablet (see page 2, second-third paras. and page 3, second para. under "Objective of the invention" of the specification).

Sue discloses a coating of a tablet for masking unpleasant odor of a plant or plant extract, particularly for masking odor of a root extract of a plant called valerian, included in the preparation, and to reduce the odor the reference discloses a three-layer coating of a tablet (see para. [0014] on page 2 and Fig. 1). Sue further discloses that the three

coating layers can be applied alone or in combination with other layers to mask the odor of a core of the tablet (see [0022] on page 3), and in the reference, the odor-masking efficiency can be evaluated by comparing smell of the tablets before and after coating of the tablet (see para. [0056] on page 6). In the disclosure of the invention of Sue, the reference merely discloses an effect of masking a taste in a parenthesis as “(and/or taste)” (see para. [0014] on page 2) and teaches that among the three layers, the second coating layer including sugars increases palatability of the preparation (see para. [0028] on page 3). Sue neither evaluates the taste of the coated tablet nor discloses a coating that can reduce an unpleasant taste or improve the taste of the tablet, other than the second coating layer including sugar.

If the second coating layer of Sue is used alone or in combination with the first and/or third layer, the coating includes sugar. Further, Sue does not teach or suggest a coating that does not include sugar but can improve the taste of a tablet, as claim 1 recites.

Sue discloses another three-layer coating, which includes a subcoat for improving adherence of a color coat to a naked core, a color coat for masking odor of the core and additionally, improving aesthetic presentation of the tablet, and gloss coat for improving aesthetics and providing a printing surface (see para. [0088] on page 10). The reference merely discloses that the color coat can improve palatability of the tablet (see *id.*) but is silent about a particular material that can improve the taste included in the color coat.

It is clear that smell and taste are different properties of a material and that the taste of the tablet cannot be evaluated by smelling. A material having a good smell can be bitter. Thus, there is no reason to assume that the formulation of Sue that can reduce or improve smell of a tablet also can improve the taste of the tablet, and Sue fails to disclose the composition that can mask an unpleasant taste of a solid core of the pharmaceutical oral solid dosage form as claim 1 recites.

In addition, the ready mix flavored composition of claim 1 can provide one layer coating that can mask an unpleasant taste of a solid core of a pharmaceutical oral solid dosage form. Even if the three-layer coating of Sue could improve the taste of valerian extracts included in the tablet core, the three-layer coating of Sue cannot provide sufficient properties necessary for pharmaceutical oral solid dosage form such as

degradation in a short period of time and sufficient dissolution of an active ingredient in the tablet. The Declaration of Mr. Sharma shows that the tablets having the three-layer coating could mask the taste but were disintegrated in 44-50 minutes and that only 21.1 % of the active ingredient in the tablet could be released when the tablets were dissolved (see coating #3 in the table on page 3 of the Declaration attached hereto). In contrast, examples 1 and 2 of claim 1 can be disintegrated in 10-11 minutes and 11-12 minutes, respectively, and 92.4 % and 90.8 % of the active ingredient can be dissolved, respectively (see *id.* at examples 1 and 2 in the table on page 2). The Declarant further found that the sweetening coating such as the coating #2 including sugar, which is particularly excluded from the composition of claim 1, is necessary to mask the taste (see *id.* at "Conclusion" on page 3 of the Declaration) and that the processing time of coating with the composition of claim 1 such as 45 minutes is significantly shorter than the time necessary for the three-layer coating such as 640 minutes in total (see *id.* at tables on pages 2 and 3).

Accordingly, claim 1, and claims 2-6 and 11-13 that ultimately depend from claim 1 are distinguished from Sue, and this rejection should be withdrawn.

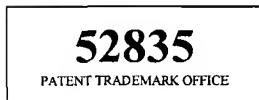
Claims 7-9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sue et al. (U.S. Patent Application Publication No. 2002/01320006) as applied above, in view of McCabe et al. (U.S. Patent No. 5,098,715). Applicants respectfully traverse this rejection.

Claims 7-9, which depend from claim 1, are distinguished from Sue for at least the same reasons as discussed for claim 1 above.

McCabe discloses a solid oral dosage pharmaceutical tablet including both sweetening agent and flavoring agent in a coating (see abstract). Even if the tablet of McCabe could mask an unpleasant taste of the tablet, the sweetening agent, which is particularly excluded from the compositions of claims 7-9, is an essential component for the coating of McCabe (see coln. 2, lines 53-57). McCabe suggests that the concentration of the sweetening agent and thickness of the coating to achieve the desired results of taste masking would be determined based on a function of the sweetening capacity of the agent (see coln. 5, lines 20-35), and the reference is silent about a coating including the

flavoring agent but no sweetening agent and further is silent about the coating including only the flavoring agent being able to mask the taste as the coating compositions of claims 7-9 can do. Thus, McCabe does not remedy the deficiencies of Sue, and claims 7-9 are distinguished from Sue in view of McCabe further in this respect. Accordingly, this rejection should be withdrawn.

In view of the above amendments and remarks, Applicants respectfully request favorable reconsideration of this application in the form of a Notice of Allowance.

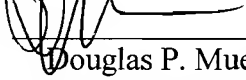


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DPM/my/jes

Respectfully submitted,

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